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PFIZER INC. PATENT DEPARTMENT, MS8260-1611 EASTERN POINT ROAD GROTON, CT 06340			LAMM, MARINA	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 02/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/636,013	Applicant(s) COLLIER ET AL.	
	Examiner Marina Lamm	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) 2-6, 12-15 and 29-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7-11 and 16-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/30/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, Claims 1-28, and species (f) in the reply filed on 11/01/05 is acknowledged. The traversal is on the ground(s) that (1) there is no undue burden upon the office in searching all of the claims; (2) the requirement is contrary to public policy; and (3) all of the original claims "are closely related to one another". This is not found persuasive because the search required for the dry powder of Group I is not required for the suspension of Group II or methods of Groups III-VI.

With respect to the election of species requirement, the election of species requirement is for examination purposes only. If the elected species is found allowable, the search will be extended to non-elected species.

The requirement is still deemed proper and is therefore made **FINAL**.

2. Claims pending are 1-78. Claims 1, 7-11 and 16-28 read on the elected species. Claims 2-6 and 12-15 have been withdrawn as directed to non-elected species. Claims 29-78 have been withdrawn from further consideration as directed to non-elected inventions.

Claim Objections

3. Claims 20, 23 and 26 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 7-11 and 16-28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,861,413 (413). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not

patentably distinct from each other because the presently claimed invention overlaps with that previously claimed. Thus, the instant claims are directed to a powder for oral suspension comprising (a) non-dihydrate azithromycin; and (b) an azithromycin conversion stabilizing excipient, which is a non-ionic surfactant (elected species). The powder of the instant claims may further comprise a conversion enhancer (e.g. a flavorant or a volatile organic component) and/or a non-viscosifying sweetener. The non-dihydrate azithromycin of the instant claims may be in the form of ethanol solvate (form F), isopropanol solvate (form M) or other forms. The claims of '413 are directed to a powder for oral suspension comprising (a) a n-propanol solvate of non-dihydrate azithromycin (form J); and (b) at least one pharmaceutically acceptable excipient. The claims of '413 do not recite the non-ionic surfactant, conversion enhancer and/or a non-viscosifying sweetener of the instant claims. However, the portion of the specification in '413 that supports the recited "at least one pharmaceutically acceptable excipient", includes the non-ionic surfactant, conversion enhancer and/or a non-viscosifying sweetener that would anticipate the instant claims. The instant claims cannot be considered patentably distinct over Claims 1 and 2 of '413 when there is a specifically disclosed embodiment in the conflicting patent that supports Claim 1 of that patent and falls within the scope of Claims 1, 7-11 and 16-28 herein because it would have been obvious to one having ordinary skill in the art to modify the composition of Claim 1 of '413 by selecting a specifically disclosed embodiment that supports that claim, i.e., the specific pharmaceutically acceptable excipients disclosed in the

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conflicting patent. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment. With respect to the Claims 20, 23 and 26 of the instant invention, the claimed ethanol solvate and isopropanol solvate of azithromycin are obvious variants of the n-propanol solvate of azithromycin claimed in '413 because they are either positional isomers (isopropanol vs. n-propanol) or homologs (ethanol vs. n-propanol). Nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer, since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. *In re Norris*, 84 USPQ 458 (1950).

6. Claims 1, 7-11 and 16-28 are directed to an invention not patentably distinct from claims 1 and 2 of commonly assigned U.S. Patent No. 6,861,413 ('413) for the reasons set forth above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. Patent No. 6,861,413 ('413), discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting

inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

7. Claims 1, 7-10, 16-20, 23 and 26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3 and 4 of copending Application No. 10/355,575 ('575). Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed invention overlaps with that previously claimed. Thus, the instant claims are directed to a powder for oral suspension comprising (a) non-dihydrate azithromycin; and (b) an azithromycin conversion stabilizing excipient, which is a non-ionic surfactant (elected species). The powder of the instant claims may further comprise a conversion enhancer (e.g. a flavorant or a volatile organic component) as discussed above. The non-dihydrate azithromycin of the instant claims may be in the form of ethanol solvate (form F), isopropanol solvate (form M) or other forms. The claims of '575 are directed to a pharmaceutical formulation comprising (a) dry granulated particles of a non-dihydrate azithromycin selected from the group consisting of forms F, G and M; and (b) optionally, one or more pharmaceutically acceptable excipients. The claims of '575 do not recite the non-ionic surfactant or conversion enhancer of the instant claims.

However, the portion of the specification in '575 that supports the recited "one or more pharmaceutically acceptable excipients", includes the non-ionic surfactant and conversion enhancers that would anticipate the instant claims. The instant claims cannot be considered patentably distinct over Claims 1, 3 and 4 of '575 when there is a specifically disclosed embodiment in the conflicting application that supports Claim 1 of that application and falls within the scope of Claims 1, 7-10, 16-20, 23 and 26 herein because it would have been obvious to one having ordinary skill in the art to modify the composition of Claim 1 of '575 by selecting a specifically disclosed embodiment that supports that claim, i.e., the specific pharmaceutically acceptable excipients disclosed in the conflicting application. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1, 7-10, 16-20, 23 and 26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 7-9, 11-14, 16-20, 25-27, 29, 31, 33-37 and 39-45 of copending Application No. 10/327,459 ('459). Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed invention overlaps with that previously claimed. Thus, the instant claims are directed to a powder for oral suspension comprising (a) non-dihydrate azithromycin; and (b) an azithromycin

conversion stabilizing excipient, which is a non-ionic surfactant (elected species). The powder of the instant claims may further comprise a conversion enhancer (e.g. a flavorant or a volatile organic component) as discussed above. The non-dihydrate azithromycin of the instant claims may be in the form of ethanol solvate (form F), isopropanol solvate (form M) or other forms. The claims of '459 are directed to a dry blend comprising (a) non-dihydrate azithromycin of form F; (b) at least one pharmaceutically acceptable excipient; and (c) a lubricant. The claims of '459 do not recite the non-ionic surfactant or conversion enhancer of the instant claims. However, the portion of the specification in '459 that supports the recited "at least pharmaceutically acceptable excipient", includes the non-ionic surfactant and conversion enhancers that would anticipate the instant claims. The instant claims cannot be considered patentably distinct over Claims 1, 5, 7-9, 11-14, 16-20, 25-27, 29, 31, 33-37 and 39-45 of '459 when there is a specifically disclosed embodiment in the conflicting application that supports Claim 1 of that application and falls within the scope of Claims 1, 7-10, 16-20, 23 and 26 herein because it would have been obvious to one having ordinary skill in the art to modify the composition of Claim 1 of '459 by selecting a specifically disclosed embodiment that supports that claim, i.e., the specific pharmaceutically acceptable excipients disclosed in the conflicting application. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment. With respect to Claim 26 of the instant invention, the claimed isopropanol solvate of azithromycin is an obvious

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variant of the ethanol solvate of azithromycin (form F) claimed in '459 because they are homologs (ethanol vs. isopropanol). One skilled in the chemical art, knowing the properties of one member of a homologous series, would generally know what to expect in adjacent members. The test of patentability of a compound that is a homologue of a prior art compound is whether the claimed compound possesses beneficial characteristics which are unexpected and unobvious. *Sterling Drug, Inc. v. Watson, Comr. Pats.* (DCDC 1955) 135 F.Supp 173, 108 USPQ 37.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1, 7-10, 16-20, 23 and 26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-37 of copending Application No. 10/327,383 ('383). Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed invention overlaps with that previously claimed. Thus, the instant claims are directed to a powder for oral suspension comprising (a) non-dihydrate azithromycin; and (b) an azithromycin conversion stabilizing excipient, which is a non-ionic surfactant (elected species). The powder of the instant claims may further comprise a conversion enhancer (e.g. a flavorant or a volatile organic component) as discussed above. The non-dihydrate azithromycin of the instant claims may be in the form of ethanol solvate (form F), isopropanol solvate (form M) or other forms. The claims of '383 are directed to a granulate comprising (a) non-dihydrate azithromycin; and (b) one or more

pharmaceutically acceptable excipients. The claims of '383 do not recite the non-ionic surfactant or conversion enhancer of the instant claims. However, the portion of the specification in '383 that supports the recited "at least one pharmaceutically acceptable excipient", includes the non-ionic surfactant and conversion enhancers that would anticipate the instant claims. The instant claims cannot be considered patentably distinct over Claims 15-37 of '383 when there is a specifically disclosed embodiment in the conflicting application that supports Claims 15, 29, 31, 34 and 37 of that application and falls within the scope of Claims 1, 7-10, 16-20, 23 and 26 herein because it would have been obvious to one having ordinary skill in the art to modify the composition of Claims 15, 29, 31, 34 and 37 of '383 by selecting a specifically disclosed embodiment that supports that claim, i.e., the specific pharmaceutically acceptable excipients disclosed in the conflicting application. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 7-10 and 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Curatolo et al. (EP 679 400).

Curatolo et al. teach a powder for oral suspension containing azithromycin, flavorants (e.g. vanilla, banana, etc.) and wetting agents such as sorbitan monolaurate and polysorbate 80. See p. 7, lines 2-37. The powder of Curatolo et al. may also contain artificial sweeteners. See p. 7, lines 20-21. The azithromycin of Curatolo et al. includes the pharmaceutically acceptable salts thereof, as well as *anhydrous* and hydrated forms. See p. 4, lines 39-40. The teaching of the "anhydrous" form of azithromycin anticipates the claimed limitation "non-dihydrated azithromycin".

Thus, Curatolo et al. teach each and every limitation of Claims 1, 7-10 and 16-19.

12. Claims 1, 7-10, 16-21, 23 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Tenengauzer et al. (US 6,764,997).

Tenengauzer et al. teach stabilized azithromycin dosage forms, including powders to make oral suspension, comprising flavorants such as vanilla, grape and banana, wetting agents such as sorbitan monolaurate and polysorbate 80, and sweeteners. See col. 5, lines 9-24; col. 6, lines 32-60. Tenengauzer et al. teach

azithromycin ethanolate monohydrate (form F) as the preferred azithromycin form. See col. 3, lines 1-6.

Thus, Tenengauzer et al. teach each and every limitation of Claims 1, 7-10, 16-21, 23 and 24.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 20, 21, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (EP 679 400) in view of either Tenengauzer et al. (US 6,764,997) or Li et al. (US 6,977,243).

Curatolo et al. applied as above. The reference does not explicitly teach the claimed forms of azithromycin. However, Tenengauzer et al. teach using azithromycin ethanolate monohydrate (form F) in stabilized powders for oral suspensions as discussed above. Alternatively, Li et al. teach using the azithromycin forms of the instant claims in pharmaceutical compositions, including powders for oral suspensions. See col. 2-4; col. 26, lines 35-36. The crystal forms of azithromycin show improved stability as compared to form A. See col. 14, lines 40-50. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Curatolo et al. such that to use azithromycin

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ethanolate monohydrate or other non-hydrate crystal forms of azithromycin instead of anhydrous azithromycin. One having ordinary skill in the art would have been motivated to do this to obtain improved stability of the compositions as suggested by either Tenengauzer et al. or Li et al.

The applied reference (Li et al.) has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

15. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (EP 679 400) in view of either Tenengauzer et al. (US 6,764,997) or

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Li et al. (US 6,977,243) as applied to claim 20 above, and further in view of Schwarz et al. (WO 2004/000865), supplied by the Applicant.

Curatolo et al. in view of either Tenengauzer et al. or Li et al. applied as above. While generally teaching artificial sweeteners, Curatolo et al. does not explicitly teach the claimed sweeteners. However, Schwarz et al. teach using aspartame as an artificial sweetener in pharmaceutical compositions comprising azithromycin monohydrate as an active ingredient. See p. 1, lines 11-19, 31-33. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Curatolo et al. such that to use aspartame of Schwarz et al. as an artificial sweetener for its art-recognized purpose. One having ordinary skill in the art would have been motivated to do this to obtain the desired taste.

16. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (EP 679 400) in view of Singer et al. (US 6,365,574), supplied by the Applicant.

Curatolo et al. applied as above. The reference does not explicitly teach the claimed ethanol solvate form of azithromycin. However, Singer et al. teach using azithromycin ethanol solvate in pharmaceutical compositions because it is less hygroscopic than azithromycin monohydrate. See col. 1, lines 60-65; col. 3, line 26. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Curatolo et al. such that to use azithromycin ethanol solvate. One having ordinary skill in the art

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would have been motivated to do this to obtain improved stability of the compositions as suggested by Singer et al.

17. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (EP 679 400) in view of Singer et al. (US 6,365,574), as applied to claim 23 above, and further in view of Schwarz et al. (WO 2004/000865), supplied by the Applicant.

Curatolo et al. in view of Singer et al. applied as above. While generally teaching artificial sweeteners, Curatolo et al. does not explicitly teach the claimed sweeteners. However, Schwarz et al. teach using aspartame as an artificial sweetener in pharmaceutical compositions comprising azithromycin monohydrate as an active ingredient. See p. 1, lines 11-19, 31-33. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Curatolo et al. such that to use aspartame of Schwarz et al. as an artificial sweetener for its art-recognized purpose. One having ordinary skill in the art would have been motivated to do this to obtain the desired taste.

18. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (EP 679 400) in view of Karimian et al. (US 6,245,903), supplied by the Applicant.

Curatolo et al. applied as above. The reference does not explicitly teach the claimed isopropanol solvate form of azithromycin. However, Karimian et al. teach using azithromycin isopropanol solvate in pharmaceutical compositions because it is a non-

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hygroscopic form of azithromycin and, therefore, is more stable than anhydrous azithromycin. See col. 2, lines 35-41; col. 3, lines 22-60. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Curatolo et al. such that to use azithromycin isopropanol solvate. One having ordinary skill in the art would have been motivated to do this to obtain improved stability of the compositions as suggested by Karimian et al.

19. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (EP 679 400) in view of Karimian et al. (US 6,245,903), as applied to claim 26 above, and further in view of Schwarz et al. (WO 2004/000865), supplied by the Applicant.

Curatolo et al. in view of Karimian et al. applied as above. While generally teaching artificial sweeteners, Curatolo et al. does not explicitly teach the claimed sweeteners. However, Schwarz et al. teach using aspartame as an artificial sweetener in pharmaceutical compositions comprising azithromycin monohydrate as an active ingredient. See p. 1, lines 11-19, 31-33. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Curatolo et al. such that to use aspartame of Schwarz et al. as an artificial sweetener for its art-recognized purpose. One having ordinary skill in the art would have been motivated to do this to obtain the desired taste.

20. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Curatolo et al. (EP 679 400) in view of Artman et al. (US 6,383,527).

Curatolo et al. applied as above. Curatolo et al. teach various flavorants as discussed previously. The reference does not teach the compounds claimed in the instant claim. However, it is well known in the art of pharmaceutical and food compositions to use isoamyl isovalerate of the instant claim as an FDA-accepted flavoring agent. See Artman et al. @ col. 8, lines 6-12. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Curatolo et al. such that to use isoamyl isovalerate for its art-recognized purpose as a flavoring agent. One having ordinary skill in the art would have been motivated to do this to obtain the desired flavor/aroma of the composition.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,633,006; US 6,068,859; US 6,277,829; US 6,475,518; US 6,703,372; US 2002/0009433; US 2004/0091527; WO 02/087596 A2.
22. No claim is allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Sreenivasan Padmanabhan, can be reached at (571) 272-0629.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Lamm
2/1/06


MICHAEL HARTLEY
PRIMARY EXAMINER